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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 10/091,897 | 03/06/2002 | Aneas Antoine | SMBIO-5708 | 9171 |
| 44444 7590 06/26/2007 BAXTER HEALTHCARE CORPORATION ONE BAXTER PARKWAY DF2-2E DEERFIELD, IL 60015 | | | EXAMINER | |
| | | | BOUCHELLE, LAURA A | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 3763 | |
| | | | . MAIL DATE | DELIVERY MODE |
| | | | 06/26/2007 | PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | T: | | | | | |
|---|---|---|--|--|--|--|--|
| \cdot | Application No. | Applicant(s) | | | | | |
| | 10/091,897 | ANTOINE, ANEAS | | | | | |
| Office Action Summary | Examiner | Art Unit | | | | | |
| | Laura A. Bouchelle | 3763 | | | | | |
| The MAILING DATE of this communication app Period for Reply | ears on the cover sheet with the c | correspondence address | | | | | |
| A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING DA Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication. If NO period for reply is specified above, the maximum statutory period was reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b). | ATE OF THIS COMMUNICATION 186(a). In no event, however, may a reply be tiruly apply and will expire SIX (6) MONTHS from cause the application to become ABANDONE | N. nely filed the mailing date of this communication. ED (35 U.S.C. § 133). | | | | | |
| Status | | | | | | | |
| 1) Responsive to communication(s) filed on 09 Ap | oril 2007. | | | | | | |
| 2a)⊠ This action is FINAL . 2b)☐ This | This action is FINAL . 2b) This action is non-final. | | | | | | |
| • | Since this application is in condition for allowance except for formal matters, prosecution as to the merits is | | | | | | |
| closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. | | | | | | | |
| Disposition of Claims | | | | | | | |
| 4)⊠ Claim(s) <u>1-16</u> is/are pending in the application. | | | | | | | |
| 4a) Of the above claim(s) is/are withdrawn from consideration. | | | | | | | |
| 5) Claim(s) is/are allowed. | | | | | | | |
| 6)⊠ Claim(s) <u>1-16</u> is/are rejected. | 6)⊠ Claim(s) <u>1-16</u> is/are rejected. | | | | | | |
| 7) Claim(s) is/are objected to. | 7) Claim(s) is/are objected to. | | | | | | |
| 8) Claim(s) are subject to restriction and/o | r election requirement. | | | | | | |
| Application Papers | | • | | | | | |
| 9) The specification is objected to by the Examine | r. | • | | | | | |
| 10) ☐ The drawing(s) filed on is/are: a) ☐ accepted or b) ☐ objected to by the Examiner. | | | | | | | |
| Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). | | | | | | | |
| Replacement drawing sheet(s) including the correct 11) The oath or declaration is objected to by the Ex | * | | | | | | |
| Priority under 35 U.S.C. § 119 | | | | | | | |
| 12) Acknowledgment is made of a claim for foreign a) All b) Some * c) None of: | priority under 35 U.S.C. § 119(a | a)-(d) or (f). | | | | | |
| 1. Certified copies of the priority documents have been received. | | | | | | | |
| 2. Certified copies of the priority documents have been received in Application No | | | | | | | |
| 3. Copies of the certified copies of the priority documents have been received in this National Stage | | | | | | | |
| application from the International Bureau (PCT Rule 17.2(a)). | | | | | | | |
| * See the attached detailed Office action for a list of the certified copies not received. | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| Attachment(s) | | | | | | | |
| 1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413) Paper No(s)/Mail Date | | | | | | | |
| 3) Information Disclosure Statement(s) (PTO/SB/08) 5) Notice of Informal Patent Application | | | | | | | |
| Paper No(s)/Mail Date 6) Other: | | | | | | | |

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The text of those sections of Title 35, U.S. Code not included in this action can be found

in a prior Office action.

2. Claims 1-8, 10, 12-14, 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over

Aneas (US 6070623) in view Bourguignon et al (US 5735841).

3. Regarding claim 1, Aneas discloses a device for connection between a closed recipient

and a container comprising a neck whose opening is closed by a stopper. Aneas discloses a base

adapted to be mounted on a recipient 3 and comprising a sleeve 12 with an inner bore 12a.

Aneas further discloses a hollow needle 5, a plunger 15, adapted to slide in the bore and has an

edge of sleeve opposite a stopper 3b provided with stop means 18 adapted to cooperate with

complementary means 16 provided on the plunger 15 to lock it in a position of transfer.

4. Regarding claims 6 and 7, Aneas discloses hooks 54 projecting radially with respect to

the sleeve that are provided with a nose.

5. Regarding claim 8, Aneas discloses a second sleeve 22 disposed radially outside an

interior sleeve 12.

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6. Regarding claim 10, Aneas discloses a means for temporarily stopping the plunger in the

disengaged position and states that the invention is in position fastened and locked on a first

receptacle, and in the inactivated position of the plunger comprising the perforating means.

7. Regarding claim 12, Aneas discloses a ready-to-use assembly comprising a closed

recipient containing a product 2, with the recipient being provided with a neck 2a whose opening

is closed by a stopper 3, with a connection device 1 mounted on said recipient. See Figs. 2-4.

8. Regarding claims 14 and 16, Aneas discloses that the device comprises an outer envelope

22 for mounting on the base.

9. Claims 1, 12, 13 differ from Aneas in calling for the needle to have a non-circular cross

section. Bourguignon teaches a connector device comprising a needle 16 having a non-circular

cross section that mates with a tubular element 42 having a corresponding non-circular cross

section to prevent rotation or misalignment thereof (Col. 2, lines 53-55). Therefore, it would

have been obvious to one of ordinary skill in the art at the time of invention to modify the device

of Aneas to include a needle and corresponding sleeve with a non-circular cross section as taught

by Bourguignon to prevent rotation of the needle.

10. Claims 2 and 3 differ from Aneas in view of Bourguignon in calling for the cross section

of the needle and the sleeve to be oval or polygonal. At the time the invention was made, it

would have been an obvious matter of design choice to form the needle and sleeve with an oval

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or polygonal cross section. Applicant has not disclosed that having an oval or polygonal cross section serves any advantage or particular purpose or solves a stated problem. Furthermore, one of ordinary skill would expect Aneas in view of Bourguignon and applicant's invention to perform equally well with either a non-circular cross section or an oval or polygonal cross section because any non-circular configuration would perform the same function as any other. Therefore, it would have been prima facie obvious to modify Aneas in view of Bourguignon to obtain the invention as specified in claims 2 and 3 because such a modification would have been

11. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Aneas in view of Bourguignon and further in view of Thibault et al (WO 99/53886).

considered a mere design consideration which fails to patentably distinguish over the prior art.

- 12. Claim 11 differs from the above teachings in calling for the stop means to comprise at least one hollow of the outer surface of the needle and at least on projection. Thibault teaches using a hollow on the outer surface of a needle (hollow above 476, Fig. 10) that is engaged by a projection that extends from the inner radial surface of a sleeve 478 (Page 14, lines 27-29). See Fig. 11. It would have been obvious to one of ordinary skill in the art at the time of invention to modify Aneas in view of Bourguignon to include a hollow in the needle and projection on the inner surface of the sleeve as taught by Thibault to keep the needle in a disengaged position.
- 13. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Aneas in view of Bourguignon in further in view of Manera (US 6706031).

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14. Claim 9 differs from the teachings above in calling for ribs that form a rigid barrier to

rotation. Manera teaches using ribs connecting an inner sleeve 12 with a plunger 15 in order to

form a rigid barrier for blocking rotation of the plunger with respect to the inner sleeve (Col. 4,

lines 41-47). It would have been obvious to one of ordinary skill in the art at the time of

invention to modify the device of Aneas in view of Bourguignon to include ribs between the

inner and outer sleeves as taught by Manera to prevent rotation of the sleeves with respect to

each other.

15. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Aneas in view of

Bourguignon in further in view of Cohen (US 4009716).

16. Claim 15 differs from the teachings above in calling for the needle to have two

penetrating ends. Cohen teaches a device having a needle with two penetrating ends 38, 40 so

that the septum 18 may maintain intact and sterile prior to use. Therefore, it would have been

obvious to one of ordinary skill in the art at the time of invention to modify the device of Aneas

in view of Bourguignon to include a needle with two penetrating ends as taught by Cohen.

Response to Arguments

17. Applicant's arguments filed 4/5/07 have been fully considered but they are not

persuasive.

- 18. Applicant argues that the stop means of Aneas are on the same side of the sleeve as the stopper. The current application requires that the edge of the sleeve opposite said stopper is provided with stop means. In the examiner's opinion, the edge of the sleeve opposite the stopper has stop means. Applicant fails to disclose whether the stop means are disposed toward or away from the stopper, only that the edge opposite the stopper has stop means.
- 19. Applicant further argues that there is no motivation to combine Aneas and Bourguignon because Aneas already has means to prevent rotation of the needle. Combining references is not analogous to adding the structural features of one device to another. Bourguignon is relied on to teach that the use of a non-circular cross section would have been obvious to one of ordinary skill in the art. There are many means well known in the art to prevent components from rotating with respect to each other. Two of such means are cooperating projection or rib as is taught by Aneas, and a non-circular cross section as taught by Bourguignon. It is a matter of obvious engineering choice to use one means over another, and therefore, there is motivation to combine the references.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO Application/Control Number: 10/091,897 Page 7

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MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura A. Bouchelle whose telephone number is 571-272-2125. The examiner can normally be reached on Monday-Friday 8-4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 517-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

NICHOLAS D. LUCCHESI

SUPERNSORY PATENT EXAMINEH TEOKKOI OGY OFNITFR 3700 Laura A Bouchelle Examiner

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